IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Hungerford et al

Serial No.

(to be assigned)

Filed:

Art Unit:

(to be assigned)

(concurrently herewith)

Examiner: (to be assigned)

For:

CELL-CULTURE AND

POLYMER CONSTRUCTS

PRELIMINARY AMENDMENT

To the Honorable Commissioner of Patents and Trademarks Washington, DC 20231

Dear Sir:

In the Specification

Specification page 2 under related applications, cancel lines 4 and 5 and substitute the following paragraph submitted in clean-form on the following sheet.

The application is related to provisional applications Serial No. 60/081,016 filed April 8, 1998 and Serial No. 60/104,842 filed October 20, 1998; and is a divisional application of Serial No. 09/275,319 filed March 24, 1999, now U. S Patent _______.

IN THE CLAIMS:

Please add new claims 36 - 83 presented in clean form on the following pages.

- 36. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy chondrocyte specimen from a different part of the patient's body, rapidly growing high-quality chondrocytes externally of the patient's body in spin-culture on microcarrier particles, and surgically implanting the rapidly grown high-quality chondrocytes into the diseased or injured tissue of the patient, such that the high-quality chondrocytes regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.
- 37. The method of claim 36, wherein the healthy chondrocyte specimen is conveniently taken from the patient's nasal septal cartilage.
- 38. The method of claim 36, wherein the rapidly grown high-quality chondrocytes are implanted for orthopedic purposes.
- 39. The method of claim 38, wherein the implantation is in the patient's knee.
- 40. The method of claim 36, wherein the high-quality chondrocytes are grown in spinculture on microcarrier particles in a reduced oxygen environment.
- 41. The method of claim 40 in which the low oxygen environment contains about 5% oxygen.
- 42. The method of claim 36, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.
- 43. The method of claim 42, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran,

N,N-diethylaminoethyl (DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.

- 44. The method of claim 42, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.
- 45. The method of claim 44, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
- 46. The method of claim 44, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.
- 47. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy chondrocyte specimen from a different part of the patient's body, rapidly growing high-quality chondrocytes externally of the patient's body in a low-oxygen environment, and surgically implanting the rapidly grown high-quality chondrocytes into the diseased or injured tissue of the patient, such that the high-quality chondrocytes regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.
- 48. The method of claim 47 in which the low oxygen environment contains about 5% oxygen.
- 49. The method of claim 47, wherein the healthy chondrocyte specimen is conveniently taken from the patient's nasal septal cartilage.

- 50. The method of claim 47, wherein the rapidly grown high-quality chondrocytes are implanted for orthopedic purposes.
- 51. The method of claim 50, wherein the implantation is in the patient's knee.
- 52. The method of claim 47, wherein the high-quality chondrocytes are grown in a low oxygen environment in spin-culture on microcarrier particles.
- 53. The method of claim 52, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.
- 54. The method of claim 53, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.
- 55. The method of claim 53, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.
- 56. The method of claim 55, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
- 57. The method of claim 55, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.
- 58. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy tissue specimen from a different part of the patient's body, rapidly growing high-quality cells from the tissue specimen externally of the

patient's body in spin-culture on microcarrier particles, and surgically implanting the rapidly grown high-quality cells into the diseased or injured tissue of the patient, such that the high-quality cells regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.

- 59. The method of claim 58, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow, periosteum, perichondrium, cartilage, bone, or peripheral blood.
- 60. The method of claim 58, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow.
- 61. The method of claim 58, wherein the cells are selected from a group consisting of chondrocytes, oesteoblasts, oesteocytes, chondrogenic cells, pluripotential cells, progenitor mesenchymal cells, fibroblasts, and mucosal cells.
- 62. The method of claim 58, wherein the rapidly grown high-quality cells are implanted for orthopedic purposes.
- 63. The method of claim 62, wherein the implantation is in the patient's knee.
- 64. The method of claim 58, wherein the high-quality cells are grown by spin-culture on microcarrier particles in a reduced oxygen environment.
- 65. The method of claim 64 in which the low oxygen environment contains about 5% oxygen.
- 66. The method of claim 58, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.

- 67. The method of claim 66, wherein the biodegradable and biocompatible material is selected from collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.
- 68. The method of claim 66, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.
- 69. The method of claim 68, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
- 70. The method of claim 68, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.
- A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy tissue specimen from a different part of the patient's body, rapidly growing high-quality cells externally of the patient's body in a low-oxygen environment, and surgically implanting the rapidly-grown high-quality cells into the diseased or injured tissue of the patient, such that the high-quality cells regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.
- 72. The method of claim 71 in which the low oxygen environment contains about 5% oxygen.

- 73. The method of claim 71, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow, periosteum, perichondrium, cartilage, bone, or peripheral blood.
- 74. The method of claim 71, wherein the healthy <u>tissue</u> specimen is conveniently taken from the patient's bone marrow.
- 75. The method of claim 71, wherein the cells are selected from a group consisting of chondrocytes, osteoblasts, osteocytes, chondrogenic cells, pluripotential cells, progenitor mesenchymal cells, fibroblasts, and mucosal cells.
- 76. The method of claim 71, wherein the rapidly grown high-quality <u>cells</u> are implanted for orthopedic purposes.
- 77. The method of claim 76, wherein the implantation is in the patient's knee.
- 78. The method of claim 71, wherein the high-quality cells are grown by spin-culture on microcarrier particles.
- 79. The method of claim 78, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.
- 80. The method of claim 79, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.
- 81. The method of claim 79, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.

- 82. The method of claim 81, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
- 83. The method of claim 81, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.

Summary

Included in the Preliminary Amendment are continuing data and additional claims.

Respectfully submitted,

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CERTIFICATE OF TRANSMITTAL

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